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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,803	01/16/2004	Daniel E. Afar	511582001310	8272

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,803	AFAR ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-44* is/are pending in the application.

4a) Of the above claim(s) *39 and 42-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The applicant has timely traversed the non-final rejection in the reply filed on 01/12/2006, and a response to the arguments is set forth.

2. Claims 1-37 have been cancelled

4. Claim 38 has been amended, and claim 39 has been withdrawn.

5. Claim 40-44 have been newly added such that claims 40 and 41 are product claims dependent upon claim 38; and claim 42 and 44 are method claims. Since the product claim was initially elected to be examined, only claims 40 and 41 are be examined along with claim 38 in this office action, but not the newly added method claims 42-44, for the reasons below:

The inventions of claims 38, 40 and 41 and the methods of claims 42-44 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide as claimed can be used in a materially different process such as antibody production in addition to the materially different methods of claims 42-44.

6. Claims 38, 40 and 41 are under examination.

7. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior office action.

Rejections Withdrawn

8. The rejection of Claim 38 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the applicants arguments.

Response to Arguments and New Grounds of Rejections

9. The Applicant has amended claim 38 to recite "an immunogenic composition for the treatment of a cancer comprising a prostate cancer treating effective amount SEQ ID NO:2 and a physiologically acceptable carrier". For the purposes of this office action, the claim is considered to read as "an immunogenic composition for the treatment of a cancer comprising a prostate cancer treating effective amount of the polypeptide comprising SEQ ID NO:2 and a physiologically acceptable carrier".

10. The rejection of Claim 38, and the newly added claims 40 and 41 under 35 U.S.C. 102(e) as being anticipated by Baker et al (U.S. Patent application publication 2003/0077712, with priority to 10/98; IDS – April 11th, 2005) is maintained and further reinstated.

The applicant argues that the provisional upon which the Baker publication claims priority, namely 60/104,987, filed on October 20, 1998, does not disclose immunogenic compositions as claimed and does not disclose overexpression in any cells and in contrast, the U.S. provisional application No. 60/128,860 upon which the

instant application claims priority was filed April 12, 1999 and discloses overexpression in prostate cancer cells and immunotherapy.

The applicants arguments are carefully considered but are not found persuasive. In response to the above arguments, the applicant is reminded that no such limitations as "overexpression in prostate cancer cells" or "immunotherapy" are recited in the claim and hence the arguments are not commensurate with the scope of the claimed invention. Further, as stated in the previous office action, a recitation as such "the treatment of a cancer" is considered as an intended use; and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

For this rejection, the recitation "for the treatment of a cancer" And "Vaccine" has not been given patentable weight.

Further, the applicant is reminded of the rejection as stated in the previous office action "Baker et al teach a polypeptide that is identical to SEQ ID NO:2 (see SEQ ID NO: 486 in Baker et al). Baker et al also teach a composition comprising the polypeptide, or an agonist, or antagonist, in combination with a pharmaceutically acceptable carrier (page 5, lines 30-32). Further, since the claim recites "immonugenic

portions" and Baker et al teach the antibodies that bind to the polypeptide (SEQ ID 486) identical to SEQ ID NO:2, it is inherent that the polypeptide taught by Baker et al consists of the "immunogenic portions" within itself. Since, the instant claim is drawn to a composition "comprising" the immunogenic portion of the polypeptide and Baker et al teach a composition consisting of the entire length of an identical polypeptide, it would be inherent that Baker et al would have the claimed composition therefore meeting the limitation of claim 38."

Similarly, claims 40 and 41 recite an intended use for the composition and hence are rejected under 102(e) as being anticipated by Baker et al for the reasons stated above.

11. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 40 is drawn to a vaccine composition for the treatment of a cancer. However, the specification provides insufficient guidance and objective evidence that such pharmaceutical compositions and or vaccines formulations would predictably invoke an anticancer or immunotherapeutic response. The specification provides no guidance on the administration of the claimed complex or any portion thereof in vivo or in vitro.

The Applicant argues that since Bodey discloses dendritic cell vaccines, which are unrelated to the proteins as presently claimed, and with regard to Bellone, et al., the disadvantages of amino acid therapy that are allegedly presented therein do not provide any evidence that the claimed peptide may not be made and used; and since Gaiger, et al describes a Wilms tumor antigen, which is not related to the claimed peptide, the office has established that a skilled artisan would be unable to make or use the composition as claimed.

In response to the above arguments, the Applicant is reminded that the art cited in the previous office action is well established in the field of cancer vaccine, which teach the unpredictability in cancer treatment, and the potential shortcomings of potential anti-cancer agents including conventional surgery, radiation and chemotherapies. In addition, the art teaches the disadvantages of peptide cancer immunotherapy in that (1) there is no direct evidence for a role in tumor rejection, (2) the therapy is applicable to few patients, (3) risk of generating tumor escape mutants, and (4) risk of autoimmune reactions. Further, there are no working examples or no indication as to the function of the claimed polypeptide (SEQ ID NO:2) as a vaccine. Thus, the reasons explained above underscores the criticality of providing workable examples which is not disclosed in the specification, particularly in an unpredictable art, such as cancer therapy.

In view of the arguments above, and the lack of guidance and or exemplification in the specification, at the time the application was filed it would not have been predictable for of skill in the art to use the pharmaceutical compositions or vaccine

formulations as contemplated in the disclosure. Thus, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

Hence claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Conclusion

12. No Claims are allowed.

13. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is

571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi Ph.D.
(571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER